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Application No.: 09/560,597
Filed: April 28, 2000
TC Art Unit: 3626
Confirmation No.: 4637

REMARKS

The foregoing Amendment is filed in response to the official action dated May 23, 2006. Reconsideration is respectfully requested.

The status of the claims is as follows:

Claims 1-14, 16-18, and 20-38 are currently pending.

Claims 1-14, 16-18, and 20-36 stand rejected.

Claims 37-38 are objected to.

Claims 1, 8, 29, and 37-38 have been amended.

The Examiner has rejected claims 1-14, 16-18, 20-25, and 28-36 under 35 U.S.C. 103(a) as being unpatentable over Colon *et al.* (USP 5,991,731) in view of Hopp (Hopp, David I., "Three topics integral to the use of the Internet for clinical trials: Connectivity, communication, and security", Drug Information Journal, Oct.-Dec. 1998). The Applicants respectfully submit, however, that the combined teachings of the Colon and Hopp references would not suggest to one of ordinary skill in this art the subject matter of amended base claims 1, 8, and 29 and the claims depending therefrom, and therefore the rejections of claims 1-14, 16-18, 20-25, and 28-36 under 35 U.S.C. 103 should be withdrawn.

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For example, claim 1, as amended, recites a method of conducting a clinical trial of a test substance over the internet from a primary site, including assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, in which the unique identifier and the unique log-in password are employed for accessing protected information from the primary site. As recited in amended claim 1, responsive to receipt by the primary site of the unique identifier and the unique log-in password, instructions are provided to the participant on using the test substance, accessing and completing at least one evaluation form from a website maintained at the primary site, and returning electronically the evaluation form to the primary site. Responsive to the receipt by the primary site of the unique identifier and the unique log-in password, the evaluation form is provided in electronic format for use by the participant, in which the evaluation form has a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form. Next, the participant completes the evaluation form. While the participant completes

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the evaluation form in electronic format, at least a portion of the question and answer section included in the evaluation form is modified based at least in part upon one or more responses provided by the participant on the evaluation form currently being completed by the participant or an evaluation form previously completed by the participant. Finally, data is compiled regarding at least one of the effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial. Such a method of conducting a clinical trial of a test substance over the internet is described throughout the instant application, for example, see page 4, line 14, to page 5, line 30, and page 13, line 22, to page 14, line 6, of the application.

The Colon reference discloses an internet-networked system for providing interactive prescription and distribution of prescriptions in conducting clinical studies. More specifically, the system disclosed by Colon *et al.* provides on-line communications to a computing center from a number of clinical study investigators at a number of diverse locations remote from the computing center (see column 1, lines 36-39, of Colon *et al.*). With respect to an initial patient visit, the Colon system causes

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a form to come up on a computer screen, allowing patient data to be entered relating to identification, demographics, and medical conditions. The information is then transmitted to a study management center 10, where an application program in an internet network server computer executes a test to see if the patient meets eligibility requirements for the study (see column 6, lines 22-43, and Fig. 1, of Colon *et al.*). If the patient is found to be eligible for the study, follow-up visits can be conducted, during which follow-up data, end-point data, and significant events data can be entered for subsequent processing (see column 7, lines 8-15, of Colon *et al.*).

The Applicants respectfully submit that the Colon reference neither teaches nor suggests, while the participant completes the evaluation form in electronic format, at least a portion of the question and answer section included in the evaluation form is modified based at least in part upon one or more responses provided by the participant on the evaluation form currently being completed by the participant or an evaluation form previously completed by the participant, as recited in amended claim 1. In the instant application, such evaluation forms in electronic format are referred to as "dynamic questionnaires" (see page 13, line 29, to page 14, line 6, of the application). By providing

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such an evaluation form in electronic format to a clinical trial participant over the internet, the participant can enter his or her answers to questions on the form, and, depending on the participant's answers, additions to or modifications of existing questions can be made on the electronic evaluation form, thereby allowing certain questions to be pursued in depth, as appropriate. Once these data are assembled, they can be stored for immediate or subsequent analysis. A new evaluation form in electronic format can then be set up for the next visit of the participant. Like the questions on the prior evaluation form, the questions on the new evaluation form may be based upon the results of the just completed form and/or one or more previously completed forms.

As discussed above, the Colon reference merely discloses, while conducting clinical studies, entering patient data on a computer-generated form during an initial patient visit and one or more follow-up visits. The Colon reference neither teaches nor suggests the advantage of being able to modify dynamically an evaluation form being completed by a clinical trial participant, particularly, while the participant is in the process of completing the form, as recited in amended claim 1.

The Hopp reference discloses various aspects relating to the use of the internet for clinical trials, such as aspects relating

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to connectivity, communication, and security. Specifically, the Hopp reference discloses providing forms for clinical trials via the internet, including contracts, protocols, informed consent forms, study procedure manuals, case report forms, draft reports, final reports, *etc.* (see page 935 of Hopp). The Applicants respectfully submit, however, that the Hopp reference fails to cure the deficiencies of the Colon reference, *i.e.*, the Hopp reference provides no hint that forms such as evaluation forms provided to clinical trial participants via the internet can be modified dynamically, particularly, while the participant is in the process of completing the form, as recited in amended claim 1. For at least these reasons, the Applicants respectfully submit that the combined teachings of the Colon and Hopp references would not suggest to one skilled in this art the subject matter of amended claim 1 and claims 2-7 depending therefrom.

For at least the reasons provided above with reference to amended claim 1, the Applicants further submit that the combined teachings of the Colon and Hopp references would not suggest to one skilled in this art the subject matter of amended claim 8 and claims 9-28 depending therefrom, and amended claim 29 and claims 30-38 depending therefrom.

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Accordingly, it is respectfully submitted that the rejections of claims 1-14, 16-18, 20-25, and 28-36 under 35 U.S.C. 103 should be withdrawn.

The Examiner has rejected claims 26-27 (which depend from amended claim 8) under 35 U.S.C. 103(a) as being unpatentable over Colon *et al.* and Hopp in view of Brin (Brin, Dinah, "Lilly warns Nutri-System about using Prozac", The Patriot Ledger, September 17, 1997, pages 5-6). The Applicants respectfully submit, however, that the Brin reference fails to cure the deficiencies of the Colon and Hopp references, and therefore the combined teachings of the Colon, Hopp, and Brin references would not suggest to one skilled in this art the subject matter of claims 26-27. Accordingly, it is respectfully submitted that the rejections of claims 26-27 under 35 U.S.C. 103 should be withdrawn.

In view of the foregoing, it is respectfully submitted that the present application is in a condition for allowance. Early and favorable action is respectfully requested.

The Examiner is encouraged to telephone the undersigned Attorney to discuss any matter that would expedite allowance of

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the present application.

Respectfully submitted,

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